

**REMARKS**

In the non-final Office Action dated March 1, 2006, claims 1-67 were examined with the result that all claims were rejected. In response, Applicant has the following comments. In view of these comments, reconsideration of this application is requested.

In the Office Action, claims 1-67 were rejected under the Doctrine of Obviousness Type Double Patenting as well as under 35 USC §102(e) as being anticipated by claims 17-29 of DeLuca et al U.S. Patent 5,843,928. It is believed that both of these rejections can be grouped together as Applicant believes the basis for patentability has a common theme which will overcome each of these two rejections.

The Examiner has noted that claims 17-29 of the prior art U.S. '928 patent are drawn to a method of treating metabolic bone disease where it is desired to maintain or increase bone mass by administering the vitamin D compound 2MD to a patient with such a disease. The Examiner has also noted that the instant claims differ from claims 17-29 of the prior art U.S. '928 patent by claiming a method for prophylaxis of a disease characterized by a need to increase the strength of a bone as well as a method for prophylaxis of osteoporosis, preventing bone fractures, and increasing egg shell strength by administering 2MD. The data contained in Tables 1 and 2 in the application as filed clearly illustrate that 2MD is unique in improving fracture strength, and the Examiner, in the previous Office Action dated June 9, 2005, has admitted that the data in Tables 1 and 2 "clearly show that 2MD is effective in increasing bone mass and bone strength of normal female rats."

Despite the fact that this rejection is a §102(e) rejection, the Examiner states at the top of page 6 of the Office Action that it would be "obvious" to one skilled in the art at the time of the invention that 2MD may be used to increase the strength of a bone, "wherever it may be needed," because the prior art is drawn to the treatment of metabolic bone disease through the increase in the strength of a bone. "The treatment is intended for the same population." Then, at the bottom of page 6 and the top of page 7 of the Office Action, the Examiner states that the discovery of a previously unappreciated

inherent property of a prior art composition "does not render the old composition new to the discoverer" and the lack of understanding or appreciation of an inherent property "did not defeat the showing of inherency."

With regard to the statements made by the Examiner that the treatment is intended for the same population, Applicant begs to differ. The claims are directed toward the prophylaxis of a disease, i.e. prevention of a disease, not the treatment of a disease. There is a distinct difference between prevention of a disease and treatment of a disease, and thus the claims are not directed or intended for the "same population" as alleged by the Examiner. The '928 reference refers to the "treatment" of metabolic bone diseases, but never refers to the "prevention" of metabolic bone diseases." This is an important distinction because there are many compounds known by those skilled in the art that might treat a disease, but do not prevent the disease. For example, there are numerous compounds which are currently used to treat various cancers. One is Taxol which is sold by Bristol-Myers Squibb as a chemotherapy drug given as a treatment for ovarian, and breast cancer. Other chemotherapy agents for treating ovarian cancer include cyclophosphamide, adriamycin, vincristin, and cisplatin. Although given as chemotherapy agents to treat cancers, none of the above five compounds would ever be given to healthy patients without cancer in an attempt to prevent a future cancer. The same is true of a steroid such as cortisone. Cortisone is a very effective anti-inflammatory medication, but no one would suggest to a person to regularly take cortisone to prevent inflammatory diseases such as bursitis or arthritis. There are obviously significant side effects to the above chemotherapy agents and steroids, and thus simply because it treats the disease does not necessarily mean that it will prevent the disease, and/or will be prescribed to prevent a disease.

The same is true of the opposite, i.e. there are drugs that prevent a disease but do not treat the disease. For example, an aspirin a day has long been touted as a means for preventing heart disease, but no one has ever suggested that an aspirin a day will treat a patient that has had a heart attack. Likewise, the intake of calcium by a healthy person

might help build bone mass so as to prevent a disease like osteoporosis, but no one would ever suggest that simply by taking more calcium you can treat osteoporosis. Thus, it is clear that the claimed compound 2MD is not being administered to the same patient population, and also clear that it would not be obvious to one skilled in the art that simply because 2MD might treat a disease that it would also prevent the disease.

With regard to the Examiner's inherency argument, the Examiner should first note that Applicant is not claiming the compound 2MD per se or a pharmaceutical composition per se. Applicant is claiming the use of 2MD for prophylaxis of a disease characterized by a need to increase the strength of a bone. Thus, the Examiner's comments regarding an "old composition" are irrelevant to the present claims.

More specifically, with regard to inherency, the evidence must be clear that the missing descriptive matter is necessarily present in the method described in the reference, and that it would so recognized by persons of ordinary skill in the art. See for example Transclean Corp. v Bridgewood Service, Inc., 290 Fed. 3rd 1346, 62 USPQ 2d, 1865, 1871 (Fed. Cir. 2002). Under the present circumstances, there is no doubt that the '928 reference cited by the Examiner does not specifically teach that the vitamin D compound 2MD could be used to prevent a disease such as osteoporosis, i.e. for the prophylaxis of a disease characterized by a need to increase the strength of a bone. The alleged inherency rejection also fails because as was stated in Ex parte Ruskin, 95 USPQ 96 (Board of Appeals 1951):

"When the examiner alleges that a certain result is inherent in the operation of a reference, it must appear that this is necessarily so without any doubt." (emphasis added)

The Examiner is basically alleging that because the '928 reference teaches the treatment of various diseases with 2MD, the administration of 2MD to treat such metabolic bone diseases will also inherently teach the prevention or prophylaxis of such diseases. Such a conclusion cannot be supported because not only does the '928 reference

never discuss or state anything about the prophylaxis or prevention of metabolic bone diseases (only the treatment of such diseases), but in view of the fact that other compounds as discussed above may be administered to treat a disease, but do not prevent the disease, how can the Examiner state that administering 2MD to treat metabolic bone diseases would also necessarily and inherently be recognized by those skilled in the art without any doubt to also prevent or be a prophylaxis against such diseases? A new use of a known compound is patentable, as long as the use is not obvious. The Examiner should specifically note that Applicant is not claiming the compound per se or a pharmaceutical composition per se. Applicant is claiming the use of 2MD for the prophylaxis of metabolic bone diseases and such use is not necessarily present in the '928 reference cited because there is nothing the Examiner can point to in the '928 reference which would suggest to one skilled in the art that the prophylaxis of metabolic bone diseases would be obvious. In addition, since there is clearly doubt as to whether a particular compound that treats a disease will also prevent the disease, the prophylaxis of metabolic bone diseases cannot be inherent in the treatment of diseases such as osteoporosis.

The Examiner's position would basically mean that any new use of known compounds would never be patentable. Just because other uses are known for a compound, one cannot immediately assume that all uses are obvious. Otherwise, one could never be able to claim a new use for a known compound, which of course is not the law. Applicant thus respectfully requests the Examiner withdraw the §102(e) rejection.

In the Office Action, claims 1-67 were rejected under 35 USC §103(a) as being unpatentable over DeLuca et al WO 02/05823. The Examiner states that the reference teaches a method of using 2MD for the treatment of metabolic bone diseases where it is desired to maintain or increase bone mass and such teaching embraces Applicant's claimed invention. The Examiner concludes that it would be obvious to one skilled in the art to use the vitamin D compound 2MD wherever increase in bone strength is needed

because the prior art '823 reference teaches the use of 2MD to increase the strength of a bone. Applicant, however, respectfully disagrees for the following reasons.

Assuming the Examiner has made a prima facie case of obviousness, Applicant may rebut that prima facie case with evidence. As stated in In re Kumar et al, 76 USPQ 2d 1048 (2005), the Court of Appeals for the Federal Circuit stated:

"An applicant may rebut a prima facie case of obviousness by providing a 'showing of facts supporting the opposite conclusion.' Such a showing dissipates the prima facie holding and requires the examiner to 'consider all of the evidence anew.' Piasecki, 745 F.2d at 1472; In re Rinehart, 531 F.2d 1048, 1052 (CCPA 1976). Rebuttal evidence may show, for example, that the claimed invention achieved unexpected results relative to the prior art, In re Geisler, 116 F.3d 1465, 1469-70 (Fed. Cir. 1997); that the prior art teaches away from the claimed invention, *id.* at 1471; that objective evidence (e.g., commercial success) supports the conclusion that the invention would not have been obvious to a skilled artisan, Piasecki, 745 F.2d at 1475; or that the prior art did not enable one skilled in the art to produce the now-claimed invention. In re Payne, 606 F.2d 303, 314-15 (CCPA 1979)."

One way referred to above in the In re Kumar et al, *supra* case that Applicant may rebut a prima facie case of obviousness is to show that the prior art did not enable one skilled in the art to produce the claimed invention. Although published subject matter is "prior art" for all that it discloses, in order to render an invention unpatentable for obviousness, the prior art must enable a person of ordinary skill in the art to make and use the invention. Thus, when a prima facie case of obviousness is made, rebuttal may take the form of evidence that the prior art does not enable the claimed subject matter. In the present circumstances, the prior art cited by the Examiner clearly does not enable the now claimed invention. There is nothing in the '823 reference which teaches one skilled in the art that the vitamin D compound 2MD may be useful for the prophylaxis or prevention of metabolic bone diseases characterized by a need to increase the strength of a bone. There

is nothing in the '823 reference which would teach this, and the '823 reference does not provide any data to support a claim to preventing or the prophylaxis of metabolic bone diseases. The closest statement found in the '823 reference referring to non-diseased states is the fact that the reference refers to increasing both breaking strength and crushing strength of bones which evidences the use of 2MD "in conjunction with bone replacement surgery such as hip and knee replacements." The '823 reference also refers to 2MD being "an excellent candidate for an anti-osteoporosis therapy" but once again, this refers to the treatment of diseases rather than the prevention of diseases.

Finally, Applicant notes that an invention is not obvious where the prior art only provides an "invitation to explore" even though the prior art could theoretically explain the invention. This is the holding in the case of Ex parte Obukowicz, 27 USPQ 2d 1063 (B.P.A.I. 1992). In Ex parte Obukowicz, the invention concerned a method of combating plant insect pests using plant colonizing bacteria that had been genetically modified to produce a specific protein toxin. The modification was accomplished by inserting DNA encoding for the protein toxin into the chromosome of the bacteria. The genetically modified bacteria were applied to the plant or plant seed environment, which expressed the insecticidally active protein toxin consumed by plant pests.

The claimed invention was rejected as obvious in view of the reference Dean combined with various secondary references. The principal issue was whether, based on Dean, the suggestion or motivation was provided to render the claimed invention obvious (i.e., the incorporation of the gene into the chromosome of bacteria that produced the protein in the plant environment).

The Board held that a statement in Dean regarding combating mosquitoes using genetically engineered "natural pond microflora" was insufficient to provide the necessary suggestion or modification. As stated by the Board:

"[T]he specific statement by Dean is not a suggestion to insert the gene into the chromosome of bacteria and apply that bacteria to the plant environment in order to protect the plant. At best, the Dean statement is but

an invitation to scientists to explore a new technology that seems a promising field of experimentation. The Dean statement is of the type that gives only general guidance and is not at all specific as to the particular form of the claimed invention and how to achieve it. Such a suggestion may make an approach "obvious to try" but it does not make the invention obvious."

The Board even added the following statement:

"We recognize that given the teachings in appellant's specification regarding incorporation of the gene into the chromosome and utilizing the bacteria in the plant environment, one can theoretically explain the technological rationale for the claimed invention using selected teachings from the references. This approach, however, has been criticized by our reviewing court as hindsight reconstruction."

Like the holding in Obukowicz, supra, the most that can be said about what is disclosed in the '823 reference referring to increasing the strength of bone is that it presents an "obvious to try" approach to the invention, but as noted above, such an approach does not make the present claimed invention obvious. The prior art '823 reference appears to provide an invitation to explore a new technology to one skilled in the art, but that does not make the present invention obvious.

An effort has been made to place this application in condition for allowance and such action is earnestly requested.

Respectfully submitted,

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